K000734

MAY - 5 2000

V. 510(K) SUMMARY

Pioneer Surgical Technology 510(K) Notification Summary For Extended GTR Device

ADMINISTRATIVE INFORMATION

Manufacturer Identification And Sponsor	Pioneer Surgical Technology 375 River Park Circle Marquette, Michigan 49855-1781 Telephone: (906) 226-9909 Facsimile: (906) 226-9932
Official Contact	Amy H. Mommaerts, Manager Regulatory Affairs
Date Prepared	March 3, 2000

DEVICE IDENTIFICATION

Proprietary Name	Extended GTR Device
Common Name	Extended GTR
Classification Name And Reference	Cerclage, Bone Fixation Regulation Number: CFR 888.3010 Classification Number: 87 JDQ Device Class: II
Devices on Which Substantial Equivalence Is Claimed	Pioneer GTR Device (K961267) and the Pioneer Bone Plate With Cerclage Cable (K940729)

Device Description

The Pioneer Extended GTR Device is based on a combination of two existing devices, the Pioneer GTR Device, 510(k) **K961267**, and the Pioneer Bone Plate with Cerclage Cable, 510(k) **K940729**.

The Extended GTR Device is essentially an extended version of the original Pioneer GTR Device; the extension being a portion of Bone Plate. The proximal portion of the Extended GTR Device is the same as the original GTR Device,

utilizing internally crimped cerclage cables, while the distal portion incorporates features of the Bone Plate, utilizing internally crimped cerclage cables and providing slots for bone screw application.

The Extended GTR Device would be offered in several configurations of length, number of bone screw holes, and number of internal crimps.

Intended Use

The Extended GTR Device is indicated for reattachment of the greater trochanter following osteotomy in total hip replacement and periprosthetic fractures of the femur. The Extended GTR may also be used for fracture of the greater trochanter.

Technological Characteristic Compared to Predicate Devices

The Extended GTR Device has the same proximal design as the long GTR Device **(K961267)**, including proximal hooks to grip the osteotomized trochanter. The distal extended plate stem design of the long GTR device is also shared. Both the Extended GTR Device and the long GTR Device include proximal and distal internally crimped cerclage cables. The cables are routed through the GTR and internal crimp, and are fastened by tightening a set screw which compresses the crimp.

The Extended GTR Device has an extended plate section that includes bone screw holes similar to the Bone Plate with Cerclage Cables **(K940729).** The two devices also share internally crimped cerclage cables, which are routed through the device and internal crimp, and are fastened by tightening a set screw which compresses the crimp.

Performance Data

The Pioneer GTR Device **(K961267)** crimping mechanism was previously tested for both static and fatigue performance (test report included in Appendix B). The Extended GTR Device has the same crimping mechanism as the Pioneer GTR Device.

Static pullout testing of the Bone Plate with Cerclage Cable **(K940729)** interconnection was previously performed (test report included in Appendix B). The Extended GTR Device has the same plate and cerclage cable interconnection as the Bone Plate with Cerclage Cable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2000

Ms. Amy H. Mommaerts
Manager, Regulatory Affairs
Pioneer Surgical Technology
375 River Park Circle
Marquette, Michigan 49855

Re: K000734
Trade Name: Extended GTR Device
Regulatory Class: II
Product Code: KTT
Dated: March 7, 2000
Received: March 7, 2000

Dear Ms. Mommaerts:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Richmond.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K000734

DEVICE NAME: Extended GTR

INDICATIONS FOR USE:

The Extended GTR Device is indicated for reattachment of the greater trochanter following osteotomy in total hip replacement and periprosthetic fractures of the femur. The Extended GTR may also be used for fracture of the greater trochanter.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-

Donna Lachner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000734